REMARKS

The Office Action dated December 1, 2006 has been reviewed and the Examiner's comments considered. Claims 1-45 are pending in this application. Claims 4 and 26-45 are withdrawn from consideration. Applicants note with appreciation the Examiner's withdrawal of the rejections in view of USPN 6,099,519 to Olsen et al. and USPN 6,058,807 to Peters.

Claim Rejections - 35 U.S.C. § 102

Claims 1, 6, 9, 10, 12, 13, and 17-19 stand rejected under 35 U.S.C. § 102(b) as anticipated by USPN 4,596,571 to Bellotti et al. (hereinafter, "Bellotti"). Applicants respectfully traverse these rejections.

Independent claim 1 recites, *inter alia*, a catheter connector including "a body comprising a cannula and a tail, said cannula extending from a distal end of said body configured to receive a catheter thereon, said tail extending from a proximal end of said body configured to receive a tube thereon...and a securement device attached to said body at said distal end..."

Bellotti shows and describes a shroud for protecting and strengthening a connection site. Referring to FIGS. 1-2, a connection system 10 to establish fluid communication between a solution container 20 and an administration set 22 includes a first connector 12 (also referred to as a spike member) attached to the end of the administration set 22 and a second connector 14 (also referred to as a tubular port member) on the solution container 20 (col. 2: ll. 50-60). Further, a shroud 18 comprising mating first and second housing shells 26 and 28 with hinge 30 is provided for connection at connection site 16 to secure spike member 12 within port 14 (col. 3: ll. 4-18). The Examiner's support in Bellotti for rejection of independent claim 1 is presented, in part, as follows:

> "Bellotti discloses a shroud for a connection site comprising a body 40 having a cannula 12 and a tail 22. Both the cannula and the tail are configured to receive a tube or a catheter thereon. The first 26 and second 28 portions of the mating connector are connected by a hinge 30. The cannula extends from a head 44." (p. 2, Office Action dated December 1, 2006).

However, contrary to the Examiner's assertion, reference numeral 22 is not the tail of a catheter connector body and is not "configured to receive a tube thereon" as claimed. Rather, reference numeral 22 is described as an administration set in Bellotti (col. 2: ll. 51-67). It should be noted that the view in FIGS. 1-2 of the administration set 22 is merely a partial cut-away view and does not show the entire length thereof (*see, e.g.,* FIG. 3 of Bellotti). As a skilled reader of Bellotti would understand, the described administration set is a component of a continuous ambulatory peritoneal dialysis (CAPD) system that carries fluid from a solution container to the abdomen of a patient. As such, the administration set is not "extending from a proximal end" of a catheter connector body, nor is it "configured to receive a tube thereon" as claimed.

Accordingly, claim 1 is believed to be patentable over Bellotti for at least these reasons. Claims 6, 9, 10, 12, 13, 17, 18, and 19 are also believed to be patentable over Bellotti, because they are dependent on a patentable claim and also because they recite additional features not shown or described by Bellotti.

Claim Rejections - 35 U.S.C. § 103

Claims 2, 3, and 7 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Bellotti in view of USPN to Clark et al. (hereinafter, "Clark"). Claim 8 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Bellotti in view of USPN 5,190,528 to Fonger et al. (hereinafter, "Fonger"). Claims 14-16 and 21-25 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Bellotti in view of WO 02/058776 to Wilson et al. (hereinafter, "Wilson") and further in view of USPAPN 2003/0065288 to Brimhall et al. (hereinafter, "Brimhall"). Finally, Claims 11 and 20 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Bellotti in view of EPO 0183396 to Bellotti (hereinafter, Bellotti II). Applicants respectfully traverse these rejections.

In view of the above, claims 2, 3, 7, 8, 11, 14-16, and 20 are dependent on independent claim 1 which is believed to be patentable in view of the above; thus, these dependent claims are also believed to be patentable. Moreover, Applicants submit that none of the cited references (viz.

Clark, Fonger, Wilson, Brimhall, or Bellotti II) properly combined with Bellotti show or describe all of the claimed elements.

Specifically, Clark does not show or describe a tail of a catheter connector body "configured to receive a tube thereon" as claimed. With particular respect to the rejection of claim 7, the Examiner points to a barbed end in Clark and posits that it would have been obvious to add the barbed end of Clark to the system of Bellotti. However, the barbed end described in Clark is an end of a catheter separate from a locking retainer that is inserted into the locking retainer. Thus, this barbed end is not a feature of a tail of a catheter connector body as claimed and, as a result, Clark does not supply the tail feature missing in Bellotti, nor are the features in Clark properly combined with Bellotti to result in the claimed invention.

Regarding Fonger and claim 8, the Examiner points to a rounded distal end of a tube 11 as providing support for the rounded edge of the cannula as claimed. However, tube 11 of Fonger is not a feature of a catheter connector body cannula, nor would it be obvious to a skilled artisan to substitute the rounded tube of Fonger for the "cannula" (spike) 12 of Bellotti, at least because the proposed modification would render Bellotti unsatisfactory for its intended purpose (i.e., the rounded spike 12 could not pierce through the membrane 24). Therefore, there is no suggestion or motivation to make the proposed modification (MPEP § 2143.01.V (p. 2100-129, MPEP 8th Ed., Rev. 5, August 2006)).

With respect to Wilson/Brimhall and claims 14-16 and 21-25, the Examiner states that it would have been obvious to modify Bellotti to include the winged covering apparatus of Wilson. The Examiner then cites to cover 34 (identified in Wilson as a connection cover 34). Claims 14-16 recite a "winged covering apparatus" while claims 21 recite a "covering being adapted for attachment to a patient." Consequently, the Wilson cover 34, which is neither winged nor adapted for attachment to a patient, is not relevant to these claims. However, Applicants will assume for purposes of this response that the Examiner meant the combination of the hub body 21 and suture wings 38, 40 instead of cover 34. In response, Applicants note that the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art

suggests the desirability of the combination (MPEP § 2143.01.III (p. 2100-128, MPEP 8th Ed., Rev. 5, August 2006)). Here, the modification of the Bellotti device to include the hub body with suture wings of Wilson is not suggested for several reasons, primarily because adding a hub body with suture wings to a device (administration set) that is intended to be suspended in air (the process of CAPD operates by gravity in most circumstances, meaning that the solution container is generally hung on a movable rack or such and the administration set is inserted into the solution container, which is remote from the user) is nonsensical as the covering would serve no purpose. Therefore, there is no suggestion or motivation to make the proposed modification. Further, with respect to claims 21-25, the recitation of "a securement device attached at two separate locations" to a distal end of a catheter connector body is not shown or described by the cited references, either alone or in combination.

Regarding Bellotti II and claims 11 and 20, the Examiner alleges that Bellotti II "teaches that the bore of the connector is funneled outward so that the bore does not engage the inserted cannula as it is advanced further into the connector." The reason for the alleged funneled bore of Bellotti II is that the bore is a feature of a sponge 48 with liquid held therein and, according to Bellotti II, it is preferable to avoid contact with the sponge during insertion of the sleeve 22 so as to prevent premature release of the liquid. Bellotti, on the other hand, shows and describes an administration set 22 with flange 44 and a solution container 20 with flange 56. The shroud 18 is configured to close over the two flanges 44, 56 (col. 3: ll. 37-61), but does not include a bore that engages any part of the spike member 12 that is within the shroud after closed around the flanges. Thus, there is no desirability of the combination of Bellotti II with Bellotti as no purpose would be served by including a tapered bore in the shroud 18. Therefore, there is no suggestion or motivation to make the proposed modification.

Accordingly, in view of the above, a prima facie case of obviousness has not been established as set forth in MPEP § 2143.03 (MPEP 8th Ed., Rev. 5, August 2006), at least because all of the claimed features are not taught or suggested by the prior art and/or there is no suggestion or motivation to make the modifications proposed by the Examiner. Therefore, claims 2, 3, 7, 8, 11, 14-16, and 20-25 are believed to be patentable over the cited combinations.

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In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 480062004300. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: February 28, 2007

Respectfully submitted,

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